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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,247	07/01/2005	Mujun Zhao	SPT-0001	6598

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WASHINGTON, DC 20036

EXAMINER

BOWMAN, AMY HUDSON

ART UNIT	PAPER NUMBER
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1635

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/541,247

Applicant(s)

ZHAO ET AL.

Examiner

Amy H. Bowman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Furthermore, under PCT Rule 13.2 the requirement of unity of invention referred to in PCT Rule 13.1 shall be fulfilled only when there is a technical relationship among these inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-3, drawn to a pharmaceutical composition comprising hLRTM4 and a pharmaceutically acceptable vehicle, classified in class 530, subclass 350.
- II. Claims 4 and 5, drawn to the use of hLRTM4 in the preparation of a drug used for treating liver injury, classified in class 514, subclass 44. **Election of this group requires further election of a specific disease or disorder from claim 5, as explained below.**

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- III. Claims 6-8, drawn to a pharmaceutical composition comprising an antisense polynucleotide to hLRTM4 and a pharmaceutically acceptable vehicle, classified in class 536, subclass 24.5.
- IV. Claims 6 and 8, drawn to a pharmaceutical composition comprising a small interfering double strand RNA of hLRTM4 and a pharmaceutically acceptable vehicle, classified in class 536, subclass 24.5.
- V. Claims 6 and 8, drawn to a pharmaceutical composition comprising an antibody against hLRTM4 and a pharmaceutically acceptable vehicle, classified in class 536, subclass 24.5.
- VI. Claims 9 and 10, drawn to the use of the antisense polynucleotide to hLRTM4 for the preparation of a drug for treating hepatocellular carcinoma, classified in class 514, subclass 44.
- VII. Claim 9, drawn to the use of the small interfering double strand RNA of hLRTM4 for the preparation of a drug for treating hepatocellular carcinoma, classified in class 514, subclass 44.
- VIII. Claim 9, drawn to the use of the antibody against hLRTM4 for the preparation of a drug for treating hepatocellular carcinoma, classified in class 514, subclass 44.

This application contains claim 5 that is directed to the following patentably distinct species: hepatitis, liver cirrhosis, or liver pathological changes caused by liver cancer. The species are independent or distinct because each of the diseases or

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disorders have different etiologic considerations and are not considered obvious variants of each other.

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed compounds, the Markush group shall be regarded as being of similar nature when

(A) all alternatives have a common property or activity and; (B)(1) a common structure is present, i.e., a significant structure is shared by all of the alternatives; or (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art-recognized class of compounds in the art to which the invention pertains.

The instant compounds are considered to be each separate inventions for the following reasons: The compounds do not meet the criteria of (A), common property or activity or (B)(2), art recognized class of compounds. The compounds each behave in a different way in the context of the claimed invention. Each member of the class cannot be substituted, one for the other, with the expectation that the same intended result would be achieved. Further, the compounds do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the antisense polynucleotides, double stranded RNAs and antibodies of the

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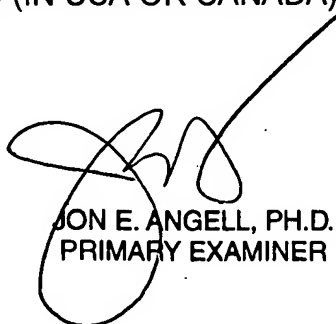
pharmaceutical compositions and methods is lacking and each compound claimed is considered to constitute a special technical feature.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


JON E. ANGELL, PH.D.
PRIMARY EXAMINER

Amy H Bowman
Examiner
Art Unit 1635

AHB